IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

GIANNA KRSTIC, Plaintiff, v. SOFREGEN MEDICAL INC., and ALLERGAN, INC., Defendants.	Case No. 1:18-cv-11585

SECOND AMENDED COMPLAINT FOR DAMAGES

Plaintiff GIANA KRSTIC, by her undersigned attorneys, brings suit against Defendants SOFREGEN MEDICAL, INC. ("Sofregen") and ALLERGAN, Inc. ("Allergan") (collectively "Allergan Defendants" or "Defendants") upon information and belief, investigation and personal knowledge, and at all times hereinafter mentioned, alleges as follows:

INTRODUCTION

1. This products liability action relates to the design, development, manufacture, testing, marketing, promotion, distribution, and sale of the SERI® Surgical Scaffold (the "Defective Device" or "the Product").

2. On July 16, 2014, the Product was surgically implanted bilaterally in Plaintiff Gianna Krstic's breasts by purportedly Board Certified plastic and reconstructive surgeon Deirdre M. Marshall, M.D. This was a bilateral breast reconstruction and implant exchange. Dr. Marshall used SERI Surgical Scaffolding in both breasts. The surgery was performed by Dr. Marshall at Kendall at South Miami Hospital, Miami, Florida.

3. The Product catastrophically failed and Ms. Krstic was required to undergo an invasive revision surgery, a total capsulectomy including an attempted removal of the implants and removal of the SERI Scaffold. This surgery was performed on September 29, 2015. This surgery caused Plaintiff to suffer significant injuries, including great pain and agony that restricted her ability to engage in activities of daily living as well as the physical activities that she enjoys. Additionally, Plaintiff suffered a significant wage loss and full disability because of the failure of the Product, injuries and ensuing complications caused by the defective Product.

4. On May 29, 2015, FDA issued a WARNING LETTER to the Quality Assurance Director at Allergan, the manufacturer, distributor, promoter, marketer and seller of SERI Surgical Scaffolds in the U.S.

5. The WARNING LETTER reported that Defendant Allergan was selling these Surgical Scaffolds without marketing clearance or approval by FDA in violation of the Federal Food, Drug, and Cosmetic Act. FDA wrote that it had reviewed the Defendant's website and found that the SERI Surgical Scaffold was adulterated and marketed in violation of section 501(f)(1)(B) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h) by Defendant Allergan.

6. FDA found that Defendant Allergan was selling the Product in violation of the Act because the Product was misbranded, among other violations.

7. Defendant Sofregen Medical Inc., a Massachusetts privately held corporation acquired SERI Surgical Scaffold from Allergan on or about November 14, 2016, and continued to market, promote and sell it in the U.S. through the present, despite significant medical problems like those experienced by Plaintiff, among others. Sofregen did nothing to change the product from the time it was sold by Allergan until the present. Sofregen simply continued the

exact same conduct in connection ti the product as had Allergan – with no substantial change noticeable by physicians or staff or patients.

PARTIES

8. Plaintiff Gianna Krstic is a resident of Raleigh, North Carolina. At all times related to this complaint, Plaintiff was a citizen of Florida.

9. Defendant Sofregen Medical, Inc. (hereinafter "Sofregen") is a corporation organized under laws of the State of Delaware, with its principal place of business located at 250 Main Street in Cambridge, Massachusetts, 02142 and as such is a citizen of both the Commonwealth of Massachusetts and the State of Delaware.

10. Defendant Sofregen was founded in 2014 to advance technology developed at Tufts University and the University of Pittsburgh. Sofregen describes itself as "a pioneer in the use of silk, nature's healing fiber, in a variety of forms to help physicians address soft tissue defects, giving patients a fresh start, restoring confidence, and improving quality of life."

11. On November 11, 2016, Sofregen posted on the BUSINESS WIRE that it is "an innovative company committed to advancing silk-based medical technologies to address soft tissue defects, today announced the acquisition of the SERI® Surgical Scaffold product line from Allergan plc. Polaris Partners and other founding investors provided financing for the transaction." https://www.businesswire.com/news/home/20161111005130/en/Sofregen-Medical-Acquires-SERI%C2%AE-Surgical-Scaffold-Product

12. Sofregen tweeted: "As the new supplier of SERI® Surgical Scaffold, Sofregen is committed to meeting the needs of customers without disruption." https://www.businesswire.com/news/home/20161111005130/en/Sofregen-Medical-Acquires-SERI%C2%AE-Surgical-Scaffold-Product

13. Sofregen began is commercial business with the acquisition of the Allergan product, SERI . Sofregen continued the sale of the SERI Product at issue in this case, after it acquired the rights to the product from Allergan in 2016.

14. Defendant Allergan, Inc. (hereinafter "Allergan") is focused on developing, manufacturing and commercializing branded pharmaceutical, device, biologic, surgical and regenerative medical products for patients around the world. Allergan, Inc.'s principal place of business in the United States is located in Irvine, California. When Allergan, Inc. communicates FDA concerning the SERI Scaffold Surgical products, Allergan uses its Boston, Massachusetts address, and previously at all times relevant, its Medford, Mass. address.

15. Serica Technologies originally developed the Product. In 2010, Defendant Allergan acquired Serica Technologies and all the scaffold products became part of the Allergan product line.

16. At all times relevant hereto, Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous prosthetic orthopedic products, including the Product, to members of the general public throughout the United States, including within the Commonwealth of Massachusetts, and including to Plaintiff 's implanting physician, or to her practice group or to South Miami Hospital where the implantation surgery occurred, and ultimately to Dr. Marshall in Miami, Florida.

17. Defendants were involved in the business of applying for market clearance to market the Product; communications with FDA concerning the Product; and reporting adverse

events concerning the Product; and the decision process and response of Defendants, if any, related to these adverse events.

JURISDICTION AND VENUE

18. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants, and because Plaintiff alleges an amount in controversy in excess of $75,000, exclusive of interest and costs.

19. The Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in the Commonwealth of Massachusetts. At all relevant times, Defendants transacted, solicited, and conducted business in Massachusetts through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Massachusetts.

20. Venue is also proper pursuant to 28 U.S.C. § 1391(c) because Defendants are all corporations that have substantial, systematic, and continuous contacts in the District of Massachusetts and are all subject to personal jurisdiction in this District.

FACTUAL ALLEGATIONS

Gianna Krstic

21. On or about July 16, 2014, Ms. Krstic underwent a total breast augmentation with insertion of the SERI® Surgical Scaffold. The surgical procedure was performed by Dr. Deirdre M. Marshall, M.D.,at South Miami Hospital in Miami, Florida.

22. Sometime after the implantation surgery, Ms. Krstic began to experience chest pain, right arm pain, swelling in her right arm and immobilization of her right arm.

23. Dr. G. Patrick Maxwell, a Board Certified plastic and reconstructive surgeon determined that Ms. Krstic had become "incapacitated in her normal lifestyle due to pain

syndrome in her right breast, chest and right upper extremity." Major Operative Report, September 29, 2015

24. After numerous visits to physicians, and multiple extensive evaluations, pain management without success, it was determined that there was a problem with the implants and with the SERI Surgical Scaffold.

25. Dr. Maxwell observed that the SERI Scaffold on Ms. Krstic's right side had hardened and scarred over internally onto her. It had not biodegraded as Allergan had represented it would do. Dr. Maxwell removed the SERI Surgical Scaffold, observed a tear in Ms. Krstic's right pectoralis muscle major, and performed a total capsulectomy. In addition, Ms. Krstic suffered an infection from the failure of the silk mesh, which infections plagued her and continued to cause her to suffer significant chest pain and require more hospitalizations.

26. Ms. Krstic was unaware that the SERI Scaffold Surgical mesh had been used at all in the reconstructive surgery performed by Dr. Marshall. Plaintiff did not know or appreciate that it was used; that it was used experimentally and without clearance by FDA; or, that it was the possible cause of her right arm immobilization, swelling or pain and her chest pains. Plaintiff first learned about the SERI mesh and its potential association with these medical problems after Dr. Maxwell's corrective surgery on September 29, 2015.

27. Plaintiff was unaware that her implanting doctor, Dr. Marshall was a paid consultant to Allergan and did not learn that information until the time of filing this lawsuit.

28. Ms. Krstic improved initially after the surgery however, by November of 2015; she was admitted to the hospital for pericarditis and pleural effusion. Dr. Maxwell referred Ms. Krstic to Dr. A. Lee Dellon at Johns Hopkins, Baltimore, Maryland, in 2017, further address the

pain and infections associated with the SERI Surgical Scaffold silk mesh from the reconstruction performed by Dr. Marshall.

29. As a result of the SERI surgical scaffolding and its failure to biodegrade, Ms. Krstic has not been able to return to her previous level of productivity. Plaintiff has suffered and continues to suffer from anxiety and depression, pain and has suffered, and will continue to suffer, a substantial wage loss. Plaintiff has been awarded 100% disability as a result of the adverse reaction and complications associated with the implantation of the Product.

30. On August 22, 2018, the Social Security Administration approved Ms. Krstic for full disability because of the failed products used during the breast surgery performed by Dr. Marshall.

31. As a result of the failure of the Product, Plaintiff's well-being has suffered, and will continue to suffer greatly. She has expended and will continue to expend money for her care, and expects to continue to suffer these losses and damages due to the ongoing pain, debilitation, and significant emotional distress, including a significant wage loss substantially caused by the Product.

II. BACKGROUND ON SERI SCAFFOLD SURGERY and SERI SCAFFOLDS

32. SERI Surgical Scaffold is a silk mesh marketed for use in plastic surgery and reconstructive surgeries to serve as the base for the body to regenerate soft tissue after medical procedures.

33. The sterile product looks similar to a silk screen and can be cut into many shapes and sizes for surgical use without tearing or fraying. Because of its flexibility, SERI Surgical Scaffold can also be used in laparoscopic surgeries and easily fits into laparoscopic tools.

34. Allergan acquired the technology when it bought Serica Technologies in 2010, a spinout from Tuft University's biomedical engineering lab run by David Kaplan and Fiorenzo Omenetto.

35. Sofregen wrote in 2016 that: "Silk has proven to promote regeneration of the body's own tissue, allowing for tremendous potential to effectively repair both disfiguring injuries and delicate defects,"

36. Sofregen chairman Howard Weisman said in prepared remarks. "The global market for products to address soft-tissue aesthetics is estimated to reach $5 billion next year. We are excited to be adding the Seri product line to our platform, and look forward to continuing to help surgeons who are eager to restore confidence and improve the quality of life for patients around the world."

37. "As the new supplier of Seri Surgical Scaffold, Sofregen is committed to meeting the needs of customers without disruption," incoming president & COO Christopher White added. "We are bolstering our commercial organization, adding field-based sales representatives and medical affairs personnel to support the Seri product line with outstanding service. We look forward to connecting with customers as we continue to innovate and grow."

38. However, FDA had warned Allergan in May 2015 about off-label marketing of the Seri scaffold for breast surgery indications, saying that this "would constitute a major change or modification to its intended use, for which your firm lacks clearance or approval."

39. Serica Technologies originally created the SERI Surgical Scaffold®® in the mid-2000s.

40. In 2010, Defendant Allergan Inc. acquired Serica Technologies and its scaffold technology.

41. Allergan describes the SERI SURGICAL SCAFFOLD on the Allergan website[1] as:

> SERI® Surgical Scaffold is a knitted, multifilament, bioengineered, long-term bioresorbable scaffold. It is derived from silk that has been BIOSILK™ purified to yield ultra pure fibroin. The device is a mechanically strong and biocompatible bioprotein. SERI® Surgical Scaffold is a sterile, single use only product and is supplied in a variety of sizes ready for use in open or laparoscopic procedures. The scaffold is flexible and well-suited for delivery through a laparoscopic trocar. It is tear resistant, with excellent suture retention, and can be cut in any direction. SERI® Surgical Scaffold provides immediate physical and mechanical stabilization of a tissue defect through its strength and porous (scaffold-like) construction. SERI® Surgical Scaffold is designed to slowly bioresorb in parallel to neovascularization and native tissue ingrowth which results in eventual replacement of SERI® Surgical Scaffold with native tissue. As bioresorption occurs, load bearing responsibility is transferred to the new tissue ingrowth such that mechanical integrity is maintained at the site.

42. The Allergan website and patent for the Product list its addresses as: Allergan, 200 Boston Ave., Medford, Mass. and Allergan, Inc. at its principal place of business in Irvine, California.

43. In November 2016, Defendant Sofregen Medical, Inc., located at 200 Boston Ave., Medford, Mass., purchased the product line in an acquisition said to "strategically [align]" with Sofregen's vision of advancing a variety of silk-based solutions to treat patients with soft-tissue defects.

44. Chairman of Sofregen Medical Howard Weisman, referred to the SERI Surgical Scaffold as "pioneering technology," and remarked on the global market's expectation for products addressing soft-tissue aesthetics to reach $5 billion in 2017.

[1] https://www.allergan.com/miscellaneous-pages/allergan-pdf-files/ifu_sclfd

45. Defendant Sofregen, and before that, Allergan, represented that the silk product would not trigger a foreign body immune response at all. Despite that representation, it did trigger a foreign body response in Plaintiff.

46. Allergan and then Sofregen represented that in surgery, doctors should place the scaffold over the area that needs support, such as the bottom and side of the breast in breast-reconstruction surgeries. The surgeon was to place stitches in the scaffold to ensure it stays in place. While in place, the scaffold reinforces and strengthens the soft tissue. As the soft tissue repairs itself post-surgery, it is intended to absorb the silk mesh over time. By the end of the process, the silk scaffold was intended to be mostly or completely reabsorbed by the body and entirely replaced with regrown soft tissue. And where the silk mesh was not reabsorbed, it was to have significantly degraded and softened.

47. However, Dr. Marshall, a paid consultant to Allergan, used the silk mesh in an uncleared manner by using it to reconstruct the breasts.

48. Plaintiff Gianna Krstic was never informed of these potential medical problems associated with the Product.

49. Plaintiff was not informed that this product would be used during the breast reconstructive surgery by Dr. Marshall; and was never informed that the Product had been associated with severe complications when used in an off-label manner.

50. Plaintiff had never been informed that the manner in which the silk mesh was to be used was not an indicated and FDA cleared use of the device.

51. Plaintiff had never been informed that Dr. Marshall had an affiliation with Sofregen or Allergan.

52. Plaintiff had never been informed that the silk mesh preented any particular risks or dangers to her.

53. Following the reconstructive surgery in which the SERI was used, Plaintiff began to suffer from right arm pain, immobilization and swelling. She reported post-surgical complications to Dr. Marshall.

54. Dr. Marshall and other physicians who saw Plaintiff initially diagnosed her as suffering from lymphedema. It was not until February 12, 2015, that she was told that she did not have lymphedema.

55. Plaintiff continued to suffer from unwarned about complications associated with and caused by the implantation of the Product into her breasts by Dr. Marshall. Plaintiff's discovery of her injuries and that their cause was delayed by the tortious conduct of Defendants and Dr. Marshall in failing to disclose the risks and dangers of these implants.

III. SERI SCAFFOLD SURGICAL MESH's REGULATORY HISTORY

56. SERIca Technologies originally submitted a request under 510(k) for market clearance to manufacture, distribute and sell the SERI Surgical Scaffold.

57. The Product was initially cleared on November 2008 by FDA as a substantially equivalent product. FDA posts on its 510(k) Premarket Notification:

Device Classification Name	Mesh, Surgical, Polymeric
510(K) Number	K080442
Device Name	SERISCAFFOLD SURGICAL MESH
Applicant	SERICA TECHNOLOGIES, INC. 200 BOSTON AVENUE SUITE 3700 Medford, MA 02155
Applicant Contact	Connie H Garrison
Correspondent	SERICA TECHNOLOGIES, INC. 200 BOSTON AVENUE

	SUITE 3700 Medford, MA 02155
Correspondent Contact	Connie H Garrison
Regulation Number	878.3300
Classification Product Code	FTL
Date Received	02/19/2008
Decision Date	11/13/2008
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General & Plastic Surgery
510k Review Panel	General & Plastic Surgery
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No
Recalls	CDRH Recalls

58. In 2013, Allergan recalled a number of products because there were sterility, validation and packaging defects in the Products sold by Allergan. That recall lasted until the end of 2013 but does not appear to have impacted the Product implanted by Dr. Marshall in July of 2014.

59. SERI Scaffold was market cleared by FDA for "use as a transitory scaffold for soft tissue support and repair to reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome."

60. The Seri Surgical Scaffold is a medical device derived from silk and used to support and repair weaknesses and voids in soft tissue in plastic and reconstructive surgery. The material is designed to dissolve or be absorbed by the body. It was studied in the U.S. in 139 patients observed for two years in a clinical trial called SURE-001. Patients underwent two-stage, implant-based breast reconstruction using Seri Surgical Scaffold.

61. In February 2015, interim data for the study was reported for 71 patients who were tracked for one year. The data revealed that the device may have caused several serious side effects and complications in patients whose doctors used it specifically for breast reconstruction.

62. These complications included tissue death, pockets of fluid, hematomas, implant loss, immune system response and infection at the surgery site.

63. On or about May 29, 2015, FDA issued a WARNING LETTER to Allergan concerning the over marketing of the Product. According to the FDA WARNING LETTER, the indications include general soft tissue reconstruction and soft tissue reinforcement in plastic and reconstructive surgery.

However, in violation of the FDA Regulations, Allergan was specifically marketing the Product for use in breast plastic or reconstructive surgery.

64. FDA reported that the breast surgery indication was outside SERI's intended use because "surgical mesh has not been cleared or approved for use in breast reconstruction using a tissue expander or implant."

65. Allergan and Sofregen, as Allergan'ssuccessor in interest in the Product, knew or should have known that the SERI Scaffold Surgical Mesh was not safe or suitable for the patients in whom it was implanted, including Ms. Krstic, because of the design of the device, failure to warn of the true complications of the Product, failure to alert FDA of the ongoing off-label use of the Product, poor and inadequate quality assurance procedures, and that it specifically was not indicated for reconstructive breast surgery for which it was sold.

66. Allergan and then, Sofregen knew or had reason to know of the failures from off-label use of the Product knew or should have known of the medical complications caused by those Product failures.

67. Allergan and then, Sofregen had a duty to alert physicians, surgeons and FDA of these expected failures and by failing to do so, and concealing the adverse events, Plaintiff and others like her, failed to get the adequate earlier care required.

68. Defendants Allergan and Sofregen failed to recognize the deficiencies of the Product due to poor and inadequate quality assurance procedures, poor or completely inadequate post marketing surveillance and adverse event reporting.

69. Defendants failed to alert the implanting physicians, their customers, of the dangers and risks of off-label use of the Product.

70. Plaintiff's implanting doctor was a paid consultant to Allergan prior to and at the time she implanted the SERI Scaffold Surgical mesh into Plaintiff. Had Defendants alerted Dr. Marshall of these medical problems associated for non-cleared uses of the Product, Dr. Marshall would have been alerted to these serious medical problems and would have alerted her patient, the Plaintiff so that both Dr. Marshall and the Plaintiff could make an informed choice based on the truth as supplied by Defendants.

71. Dr. Marshall used the Product in an off-label manner. Had Defendants alerted Dr. Marshall to these medical problems caused by off-label use, Dr. Marshall could have made an educated decision of whether or not to even use the Product in this manner.

72. Had Plaintiff or her doctors had known that the Silk mesh did not properly degrade, and could cause hardening of the mesh under and around the breast reconstruction and the implants, resulting in hardening of the tissues, and related medical problems Had Plaintiff or her doctors had known that the Silk mesh did not properly degrade, and could cause hardening of the mesh under and around the breast reconstruction and the implants, resulting in hardening of the tissues, and related medical problems, Plaintiff and/or her doctors could and would have recognized the symptoms of her chest pain, arm swelling, limb immobilization and pain by earlier intervention.

73. As a result of the Product's defects and Defendants' tortious acts/omissions, Plaintiff, and many other patients who received these Products, endured unnecessary pain and suffering; debilitating lack of mobility; and subsequent surgeries to replace the faulty Product and address complications arising from the Product and revision surgeries, giving rise to more pain and suffering, a prolonged recovery time, and an increased risk of complications and risk of death from surgeries.

74. Plaintiff and those like her have suffered from unnecessary pain, debilitation, hospitalization, and the need to undergo subsequent revision surgeries because Defendants defectively designed the Product and/or failed to adequately warn of the dangers of the Product.

IV. VIOLATIONS OF FEDERAL REGULATIONS

75. The Medical Device Amendments of 1976 ("MDA") to the Food Device Cosmetic Act ("FDCA") established the current regulatory framework for medical device approval.

76. According to the U.S. Supreme Court in Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341, 346 (2001), the Supreme Court explained that: "[s]ection 510(k) submissions must include the following: 'Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use,' 21 CFR § 807.87(e) (2000); and must include "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," § 807.87(f); "[a] statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted," § 807.87(k); and "any additional information regarding the device requested by the [FDA] Commissioner that is necessary for the Commissioner to make a

finding as to whether or not the device is substantially equivalent to a device in commercial distribution," § 807.87(l). Here, the Product was cleared pursuant to this 510(k) process.

77. The FDCA requires cleared medical devices to be demonstrated to be safe and effective for each intended use. See 21 U.S.C. § 360e(c)(2)(A)(v). Not only is the medical device itself part of the 510(k) process, but so is the labeling and packaging that comes with it.

78. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. See 21 U.S.C. §352.

79. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. §351.

80. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any of its medical devices may have caused or contributed to death or serious injury, or if the devices have malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. §360(i).

81. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that (a) a device may have caused or contributed to death or serious injury, or (b) that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. See 21 CFR §803.50.

82. Pursuant to federal regulations, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken with regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. See 21 CFR §803.52.

83. Pursuant to federal regulations, manufacturers must report any reportable Medical Device Reporting ("MDR") event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, to the FDA within 5 business days after becoming aware of such event or events. See 21 CFR §803.53.

84. Pursuant to federal regulations, device manufacturers must report promptly to FDA any device corrections and removals and must also maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device which may present a risk to health. The written submission must contain, among other things, a description of the

event giving rise to the information reported, the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. See 21 CFR §806.

85. Pursuant to federal regulations, manufacturers must comply with specific quality system requirements promulgated by FDA. These Regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to define user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production of the devices. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Further, manufacturers are required to use statistical techniques, where necessary, to evaluate product performance. See 21 CFR §820.

86. Pursuant to federal regulations, a manufacturer must report to the FDA any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of its devices. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." See 21 CFR §814.

87. Specifically, it is believed that with respect to the Product, the Allergan Defendants sold the Product for the intended us of breast augmentation and breast plastic surgery and reconstruction without clearance by FDA.

88. The Product was marketed and sold by the Allergan Defendants in violation of certain Federal Regulations. Upon information and belief, Defendants intentionally marketed and sold the Product for a nonindicated use, failed to timely report adverse events; failed to timely conduct failure investigations and analyses; failed to timely report any and all information concerning product failures and corrections; failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or device modification; failed to conduct necessary design validation; and, among other things, sold a misbranded and adulterated product.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
NEGLIGENCE

89. Plaintiff adopts and re-alleges the allegations contained in the above paragraphs as if set forth fully herein.

90. Defendants designed, manufactured, marketed, detailed, advertised, and sold to physicians and consumers the Products.

91. Defendants owed Plaintiff a duty of care and Defendants breached that duty, and that the breach caused Plaintiff to suffer injuries and damages.

92. Defendants breached their duty by failing to exercise reasonable care in the formulation, manufacture, marketing, advertising, distribution, and sale and post marketing surveillance of the SERI Products.

93. As a direct and proximate result of Defendants' failure to exercise reasonable care in the formulation, manufacture, marketing, advertising, distribution, and sale of the SERI Product, Plaintiff suffered damages injuries and damages as set forth in detail below.

94. As a result, Defendants had a duty to exercise reasonable care in the design, formulation, manufacture, testing, quality assurance, quality control, labeling, marketing, warning, sale and/or distribution of the Product, including:

a. a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events; and/or

b. a duty to adequately warn foreseeable users of known or reasonably known dangers.

95. Defendants failed to use reasonable and due care for the safety and well-being of those in whom the Product would be implanted, including Plaintiff herein and is therefore negligent in the following respects:

a. Defendants failed to adequately design and manufacture the Product to ensure that the Product could perform as represented and would bioabsorb into the surrounding tissue and form a strong structure for the new native tissue;

b. Defendants failed to warn implanting surgeons, such as Dr. Marshall, and the patients, such as Plaintiff, of the increased risk of failure of the implanted silk mesh used as a scaffold for the reconstruction of soft tissue especially in the breast;

c. Defendants were negligent in designing and manufacturing the Product such that it was subject to failure to reabsorb, due to a combination of the failure of the mesh to reabsorb and the normal immune reaction to a foreign object, and in some cases to actual

infection with microorganisms, the silk mesh starts to cause the native tissue to disintegrate, and the need for revision surgery;

d. Defendants, furthermore, in advertising, marketing, promoting, packaging and selling the Devices negligently misrepresented material facts regarding their safety, efficacy and fitness for human use by claiming the Product was fit for its intended purpose when, in fact, it was not;

e. Defendants, in advertising, marketing, promoting, packaging and selling the Product, negligently misrepresented material facts regarding its safety, efficacy and fitness for human use by claiming the Product had been adequately and reliably tested when, in fact, it had not;

f. Defendants, in advertising, marketing, promoting, packaging and selling the Product, negligently misrepresented material facts regarding its safety, efficacy and fitness for human use by claiming the risk of serious adverse events and/or effects from the Product; and,

g. Defendants, in advertising, marketing, promoting, packaging and selling the Product, negligently misrepresented material facts regarding its safety, efficacy and fitness for human use by claiming the Product had not caused or contributed to serious adverse events and/or effects requiring the premature explants of the device when, in fact, it had.

96. Defendants knew or reasonably should have known of the true risks and dangers associated with the manner and circumstances of Plaintiff Ms. Krstic's foreseeable use of the Product, which dangers would not be obvious to the general public.

97. Defendants knew or had reason to know that Plaintiff Ms. Krstic, as a member of the general public for whose use the Product was placed into interstate commerce in Florida, was

a foreseeable user who would be likely to use the Product in a manner described in this Complaint.

98. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.

99. Despite the fact that Defendants knew or should have known that the Product posed a serious risk of bodily harm to consumers, they continued to manufacture, market, distribute and sell this Product for use by plastic and reconstructive surgeons for use in their patients and continued to fail to adequately warn foreseeable users of the Product's dangers.

100. Prior to and at the time that Dr. Marshall performed the breast reconstruction surgery for Plaintiff Ms. Krstic in 2014, Allergan knew or should have known that the SERI Product was defective for the reasons described herein, and had the opportunity and duty to warn Dr. Marshall and Plaintiff Ms. Krstic of the true risks and dangers inherent in the use of the Product when used off-label in the manner in which Allergan sold it for use by Dr. Marshall.

101. Despite the fact that Allergan knew or should have known of the true risks and dangers in connection with the use of this Product, Allergan failed to warn Dr. Marshall or Plaintiff Krstic of the risks and true dangers of use of the product in the off label manner for which Allergan sold and marketed the SERI Product. Allergan's conduct, as described above, including, but not limited to, the failure to adequately test and warn, failure to obtain market clearance from FDA as well as marketing and distribution of the SERI Product when Defendants knew or should have known of the serious health risks these devices created, was negligent and the breach of that duty resulted in the harm suffered by Plaintiff.

102. Defendants misrepresented the successful use of the Product, when Defendants knew or should have known that these representations were indeed not accurate or true..

103. As a direct and proximate result of Defendants' negligence, including negligent testing, failure to warn and misrepresentations, Plaintiff Krstic suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

104. As a direct and proximate result of Defendants' ongoing failure to warn patients and their doctors of post market safety concerns such as the fact that the SERI Product did not reabsorb, but scarred over and the SERI Product caused an inflammatory reaction or foreign body reaction with multiple medical sequellae, pateitns including Plaintiff suffered multiple medical problems without understanding the reason for the problem.

105. Defendants knew or had reason to know of these serious medical consequences of off-label use of the SERI Product in breast augmentation and breast reconstructive surgery, but yet, ignored these dangerous risks and continued the silent disregard of the safety and well-being of the patients in whom the SERI Products had been used in an off label and dangerous manner.

106. As a direct and proximate result of Defendants' negligence, Plaintiff Krstic has suffered and will continue to suffer injuries, ongoing medical problems and medical procedures, emotional and physical damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

SECOND CLAIM FOR RELIEF
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

107. Plaintiff adopts and re-alleges the allegations contained in the above paragraphs as if set forth fully herein.

108. Defendants had a duty to design, manufacture, place into the stream of commerce, distribute, market, promote and sell, the Product so that it was neither defective nor unreasonably

dangerous when put to the use for which it was designed, manufactured, distributed, marketed and sold.

109. At all times relevant to this Complaint, the Defendants were engaged in the business of designing, manufacturing, marketing, distributing and selling orthopedic hip implants and did design, manufacture, distribute, market and sell the Product.

110. The Allergan Defendants did in fact design, manufacture, sell, distribute, supply, and/or promote the Product to Plaintiff Krstic and her implanting physician. Defendants expected the Product they were selling, distributing, supplying, manufacturing and/or promoting to reach, and it did in fact reach, implanting physicians and consumers, including Plaintiff Krstic and Dr. Marshall, without substantial change in the condition.

111. At the time the Product left the Defendants' possession and the time the Product entered the stream of commerce in the State of Florida, it was in an unreasonably dangerous or defective condition, due to defects including but not limited to, the following:

a. the Product was not reasonably safe as intended to be used;

b. the Product had an inadequate design for the purpose of breast reconstruction;

c. the Product contained unreasonably dangerous design defects, including an inherently unstable and defective design, which resulted in an unreasonably high probability of early failure;

d. the Product's unstable and defective design resulted in the Product, which had risks which exceeded the benefits of the medical device;

e. the Product was not appropriately or adequately tested before its distribution; and

f. the Product had an unreasonably high propensity for failure to reabsorb, for failure to accept and hold the weight of a reconstructed breast under the known about and marketed off-label use of the Product;

g. the Product was improperly marketed by Defendants for an off label use;

h. Defendants improperly marketed with Product without disclosing the true risks and dangers of the Product used in breast augmentation and breast reconstructive surgery.

112. At the time of the Allergan Defendants' initial design, manufacture, marketing, and sale of the Product, including prior to the time of Plaintiff Krstic's initial breast reconstructive surgery, Defendants had the ability to eliminate the unsafe character of the Product without impairing its usefulness.

113. Had Defendants properly and adequately tested the Product, Defendants would have discovered that the Product did not perform in the manner represented and could not withstand stress resulting from the ordinary wear and tear of patients, and was likely to cause tissue necrosis, hardening of the Product and adjacent tissue, immunological response, infections, and a host of other maladies.

114. The Product manufactured and supplied by the Allergan Defendants was, therefore, defective in design or formulation in that, when it left the hands of Defendants, it was unreasonably dangerous and more dangerous than an ordinary consumer would expect.

115. The warnings (pre-surgery and/or post-surgery) to Plaintiff Krstic and her implanting and revising physician about the dangers the Product posed to consumers were inadequate. Examples of the lack and/or inadequacy of Defendants' warnings include, but are not limited to, one or more of the following particulars:

a. the Product contained warnings insufficient to alert Plaintiff Krstic and her physician as to the excessively high rate of premature failure of the Product;the Product contained misleading warnings emphasizing the efficacy of the Product while downplaying the risks associated with it, thereby making use of the Product more dangerous than the ordinary consumer would expect;

b. the Product contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff Krstic, through their prescribing physician regarding the risk, scope, propensity, frequency, duration and severity of the adverse events associated with the Product;

c. the Product's warnings did not disclose that it was inadequately tested;

d. the Product's warnings and instructions failed to convey adequate post-marketing warnings regarding the risk, severity, propensity, frequency, scope and/or duration of the dangers posed by the Product;

e. the Product failed to contain instructions sufficient to alert consumers to the dangers it posed and to give them the information necessary to avoid or mitigate those dangers; and

116. Plaintiff Krstic could not have discovered any defect in the Product through the exercise of due care.

117. Defendants, as designers, manufacturers, distributors, promoters, marketers and/or sellers of medical devices are held to the level of knowledge of experts in their field.

118. Neither Plaintiff Krstic nor her implanting physician had substantially the same knowledge about the Product as Defendants.

119. Defendants knew or reasonably should have known the Product was unsuited for active individuals such as Plaintiff Krstic.

120. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff Krstic has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, full disability and other damages, as set forth herein.

121. As a direct result of Defendants' failure to warn and/or inadequate warning and their other tortious conduct, Plaintiff Krstic has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

122. As a direct and proximate result of Defendants' failure to warn and/or inadequate warning and their other tortious conduct, as set forth herein, Plaintiff Krstic has suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

123. As a direct and proximate result of Plaintiff Krstic's use of the Product, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff Krstic has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

124. As a direct and proximate result of Defendants' defective product and tortious conduct as set forth herein, Plaintiff Krstic has suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact.

THIRD CLAIM FOR RELIEF
FRAUDULENT CONCEALMENT

125. Plaintiff adopts and re-alleges the averments contained in the above paragraphs as if set forth fully herein.

126. Allergan and Serica Technology, as the designers, manufacturers, and sellers of the Product had knowledge of material facts about the quality, safety, and effectiveness of the Product that was superior to the knowledge that Plaintiff and Plaintiff's surgeon possessed or could have possessed.

127. Sofregen, who acquired and continued to market and sell this product in 2016 through th present, had knowledge of material facts about the quality, safety, and effectiveness of the Product that was superior to the knowledge that Plaintiff and Plaintiff's surgeon possessed or could have possessed. Defendants' knowledge that the Product was associated with an increased risk of failure with marketed for off-label use of the Product was not available to the public or medical community. This is so because the Allergan Defendants had exclusive knowledge about, and possession, of the following:

a. Pre-market documents, including the Design History and Risk Management Files. These files are required for medical devices that can cause or contribute to death, serious illness, or injury and document that medical device manufacturers are complying with design controls. The files include information about: the design inputs, which are the product requirements that include the physical and performance characteristics of the device that are used as a basis for device design; design outputs—known as the product specifications, which are broadly speaking the "blueprints" for the product; design verifications and validations, which are the test protocols and test reports to confirm the products meet the design requirements and specifications and conform to user needs and intended uses; engineering change orders,

which are intended design changes; internal audit reports of the Design History File; and device/design failure modes and effects analysis, which identifies possible failures in a design or manufacturing process.

b. Regulatory submissions. This includes premarket notification and all communications related to the clearance from and to the FDA; letters to file regarding modifications to the Product that are not reported to the FDA; and correction and removal reports to the FDA, which is any correction or removal of a medical device if the correction or removal was initiated to reduce a risk to health posed by the device.

c. Post-market surveillance. This includes complaint files with documents that are not in the public domain; corrective and preventive action files with documents that are not in the public domain such as Health Hazard Evaluations and verifications or validation reports, which are used to identify and investigate product and quality problems, and full Medical Device Reports that report adverse events.

128. Allergan and Sofregen have an ongoing and a special relationship with plastic surgeons, and thus a duty to doctors that significantly exceeds the duty between ordinary buyers and sellers, because doctors, such as Dr. Marshall, rely on information from medical device manufacturers and they expect this information to be truthful. For this reason, Defendants knew or should have known that surgeons rely on information provided by them.

129. Defendants affirmatively misrepresented that off-label use was safe and effective when Defendants knew or had reason to know that was untruthful.

130. In addition, prior to Plaintiff Krstic's implanting surgery and continuing through her revision surgery, Defendants knew that the Product was defective and unreasonably dangerous for its intended purpose because it was associated with an increased risk of failure

with ordinary use of the Product but failed to exclude that material information to the plastic and reconstructive surgery community, thereby concealing and/or impeding the critical care that Plaintiff needed.

131. With full knowledge of the risks and/or defects, Defendants consciously, deliberately and intentionally failed to disclose and misrepresented material facts to Plaintiff Krstic and her implanting physician, with the intent of inducing the physician to use the product.

132. Defendants' fraudulent concealment of the true facts that the Product was associated with an increased risk of failure of the Product continued through the time of Plaintiff Krstic's revision surgery in November of 2015. This fraudulent concealment led to a worse outcome for Ms. Krstic. Defendants were responsible for these omissions and failure to disclose.

133. Defendants were responsible for training all sales representatives who sold Wright products.

134. In training the sales representatives, Defendants did not disclose the risks of a higher prevalence for failure and resulting medical problems including infection, hardening of the silk mesh, and destruction of the implants and adjacent tissue, and the need for patients to be monitored accordingly and undergo revision surgery. Accordingly, prior to Plaintiff Krstic's implanting surgery and continuing through her revision surgery, the sales representatives who sold the Product to Dr. Marshall, did not disclose the above-mentioned risks to Plaintiff's surgeon or Plaintiff.

135. The facts concealed or not disclosed by Defendants to Plaintiff and Plaintiff's surgeon were material facts that a reasonable person, including Plaintiff Krstic and her implanting surgeon, would have considered to be important in deciding whether or not to undergo a procedure or surgery using the Product.

136. Plaintiff and Plaintiff's surgeon relied on representations and information provided by the Allergan Defendants, which is demonstrated by the fact that Plaintiff was implanted with the Product and not warned of the increased risk of failure, and the need to be monitored accordingly and the potential for revision surgery. Had Defendants disclosed these risks, Plaintiff would not have consented to the implantation of the Product and would not have suffered a catastrophic failure.

137. As a direct and proximate result of Defendants' failure to adequately communicate a warning and/or failure to provide an adequate warning and other wrongful conduct as set forth herein, Plaintiff Krstic has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses, full disability, and other damages, as set forth herein.

138. As a direct and proximate result of Defendants' failure to warn and/or inadequate warning and their other tortious conduct, as set forth herein, Plaintiff Krstic has suffered and will continue to suffer injuries, damages and losses, and is entitled to compensatory damages in an amount to be determined by the trier of fact. Additionally, Plaintiff Krstic is entitled to recover such damages from Defendants as may be permitted by Florida law for the fraud and suppression of information as set forth above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants, and each of them, in an amount which exceeds the jurisdictional limits of all lower courts, together with interests, costs, and disbursements of this action, including damages including, but not limited to:

a. for special damages, to include past and future medical and incidental expenses, according to proof;

b. for past and future loss of earnings and/or earning capacity, according to proof;

c. for past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;

d. for pre-judgment and post-judgment interest;

e. for the costs of this action, including reasonable attorneys' fees; and

f. granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests a trial by jury of all issues triable by jury.

GIANNA KRSTIC,
By Her Attorney,

Dated: April 10, 2019

/s/ Paula S. Bliss

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on April 10, 2019.

/s/ Paula S. Bliss